

REMARKS

Summary of Office Action

As an initial matter, Applicants note with appreciation that in view of the Appeal Brief filed March 29, 2010 prosecution has been reopened and all rejections set forth in the previous Office Action appear to have been withdrawn.

Claims 49, 50 and 53 are newly rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Williams et al., GB 2280111 (hereafter “WILLIAMS”).

Claims 34-57 are newly rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Guskey et al., U.S. Patent No. 5,776,494 (hereafter “GUSKEY”) in view of Bhakoo et al., US 2003/0059396 A1 (hereafter “BHAKOO”) and Hei et al., U.S. Patent No. 6,593,283 (hereafter “HEI”).

Claims 34-36, 38-45 and 47 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 46-56 and 64 of copending Application No. 10/574,219.

Claims 34-36 and 38-45 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 46-48, 54-61 and 63 of copending Application No. 10/574,230.

Claims 34-36, 38-45 and 47 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 43, 51-53, 56-59, 64, 75 and 81 of copending Application No. 11/586,585.

Response to Office Action

Reconsideration and withdrawal of the rejections of record are respectfully requested, in view of the following remarks.

Response to Rejection of Claims under 35 U.S.C. § 102(b)

Claims 49, 50 and 53 are newly rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by WILLIAMS. The rejection specifically relies upon Example 9 of WILLIAMS and alleges that this Example discloses a clear gel containing 20% aluminum chlorohydrate (which allegedly is a combination of aluminum chlorohydrate and propylene glycol), 0.5% lactic acid and water. The rejection further alleges that “[s]ince the composition is taught as a gel, the antiperspirant, acid, and water are present in a ratio that resulted in gelling.”

Applicants respectfully traverse this rejection. In particular, the Examiner’s allegation that merely because Example 9 of WILLIAMS describes the composition as containing the three components recited in claim 49 and also describes the composition as being a gel clearly does not mean, let alone necessarily mean, that the three components recited in claim 49 are present in ratios which result in gelling.

For example, the fact that the composition of Example 9 of WILLIAMS is described to be a gel can reasonably be explained by the fact that the composition contains 3 % by weight of dibenzylidene sorbitol, i.e., a substance which is expressly mentioned in WILLIAMS as the preferred gelling agent for use in the clear gel antiperspirant compositions of WILLIAMS. In this regard see, for example, page 7, lines 15-21 of WILLIAMS. In contrast, lactic acid is mentioned in WILLIAMS as one of several examples of buffering agents which are generally used in the

compositions of WILLIAMS in an amount between 0.1 to 3 % by weight of the composition (see page 6, line 24 to page 7, line 14 of WILLIAMS).

In view of the foregoing facts it is apparent that there is no basis whatsoever for the assumption that the composition of Example 9 would have been a gel even without the presence of 3 % by weight of dibenzylidene sorbitol therein. In this regard, it also is to be noted that the amount of water in the composition of Example 9 of WILLIAMS, i.e., about 5 % by weight, is relatively small, which is yet another reason why there is no reasonable basis to believe that the composition of Example 9 of WILLIAMS would have gelled in the absence of dibenzylidene sorbitol (for example, in comparison, all of the compositions which are exemplified in the instant specification comprise at least 87 % by weight of water, which is much more than the two remaining components recited in instant claim 49).

The Examiner further is reminded that matter is "inherent" if the extrinsic evidence makes it clear that the matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. *Titanium Metals Corp. v. Banner*, 778 F.2d 775 (Fed. Cir. 1985); *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349-50 (Fed. Cir. 2002); *In re Crish*, 393 F.3d 1253, 1258-59 (Fed. Cir. 2004). Inherency, however, cannot arise from probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. To the contrary, a certain thing must result from a given set of circumstances to be inherent. *In re Robertson*, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999).

Applicants submit that for at least all of the foregoing reasons, the instant rejection under 35 U.S.C. § 102(b) is without merit and should be withdrawn, which action is respectfully requested.

Response to Rejection of Claims under 35 U.S.C. § 103(a)

Claims 34-57, i.e., all claims of record, are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over GUSKEY in view of BHAKOO and HEI. The rejection essentially alleges that GUSKEY teaches a topical pharmaceutical composition comprising at least one active agent, a gelling agent, and an anhydrous solvent and that among the active agents, aluminum and aluminum-zirconium chlorohydrate and mandelic acid are mentioned. The rejection also notes that although GUSKEY teaches that an anhydrous solvent is used, GUSKEY also teaches that the anhydrous solvent may contain up to 5 % of water. The rejection concedes that "Guskey et al. do not exemplify an embodiment that contains the specific active agents in the claimed ratios" but essentially alleges that this deficiency of GUSKEY is cured by BHAKOO and HEI.

Applicants respectfully traverse this rejection for all of the reasons which are set forth in the responses to the previous Office Actions and in the Appeal Brief filed March 29, 2010. The corresponding remarks are expressly incorporated herein.

It is pointed out again that GUSKEY (i) discourages the use of water in any amount in the compositions disclosed therein and (ii) neither teaches nor suggests that an antiperspirant active ingredient, an α -hydroxycarboxylic acid and water should be present in these compositions in ratios which result in gelling.

Regarding (i), GUSKEY states in col. 10, lines 21-35 thereof (emphasis added):

The anhydrous liquid carrier preferably comprises one or more anhydrous liquids suitable for topical application to human skin, which carrier or combination of liquid carriers are liquid under ambient conditions. The term "anhydrous" as used herein means that the pharmaceutical gel compositions of the present invention, and the essential or optional components thereof other than the pharmaceutically acceptable actives, are substantially free of added or free water. From a formulation standpoint, this means that the pharmaceutical gel compositions of the present invention preferably contain less than about 5%, preferably less than about 3%, more preferably less than about 1%, most preferably zero percent, by weight of

free or added water, other than the water of hydration typically associated with the pharmaceutically acceptable actives prior to formulation.

Accordingly, even if GUSKEY indicates that the presence of (unintentionally present) small amounts of water in the compositions disclosed therein can be tolerated, GUSKEY nevertheless provides a clear teaching that water is most preferably completely absent from these compositions. It is not seen that this provides an apparent reason for one of ordinary skill in the art to intentionally employ water in any amount in the compositions according to the teaching of GUSKEY (let alone to employ water intentionally in an amount which results in a ratio with respect to antiperspirant active agent and α -hydroxycarboxylic acid that results in gelling).

Applicants note that the Examiner takes the position that GUSKEY “only prefers that the amount of water be limited to a relatively small amount (less than 5%). There is no teaching in Guskey that water adversely affects the functioning of the composition, and as embodiments containing more water are not disparaged or otherwise taught unsuitable, these embodiments would not amount to a teaching away”. Page 8, last paragraph of the instant Office Action.

Applicants respectfully disagree with the Examiner in this regard. In particular, GUSKEY explicitly states that the amount of water in the compositions disclosed therein is most preferably zero percent. Further, the relevant question here is not whether or not GUSKEY teaches away from using significant amounts of water in the compositions disclosed therein, but whether GUSKEY provides an apparent reason for one of ordinary skill in the art to employ any water at all in the “anhydrous liquid carrier”, i.e., component C.) of the pharmaceutical compositions described and claimed therein. At any rate, it is fair to state that according to GUSKEY water is an undesirable component of the compositions taught therein. It is necessary for the Examiner to properly construe what an applied reference *fairly* teaches or discloses. See, e.g., *In re Fracalossi and Wajer*, 681 F.2d

In view of the foregoing, it is apparent that even if one were to assume, *arguendo*, that the concentration of water in the compositions of GUSKEY can be unlimited, there would be no apparent reason for one of ordinary skill in the art to adjust the amount of water with respect to antiperspirant active agent and α -hydroxycarboxylic acid so that the ratio of these three components results in gelling because even under the most lenient standard of interpreting the disclosure of GUSKEY it is not seen that water is represented as a critical component of the compositions disclosed therein and accordingly, there is no reason whatsoever to adjust the amount of water in the compositions of GUSKEY in order to achieve any result and in particular, gelling.

At any rate, the compositions of GUSKEY already contain a gelling agent, i.e., an agent whose very purpose is to cause the formation of a gel, wherefore there would not reason whatsoever to adjust the ratio of water and/or any other components of the composition of GUSKEY to result in gelling. In other words, the gelling is taken care of by the presence of a gelling agent, i.e., component B.) of the pharmaceutical compositions of GUSKEY.

Applicants note that the Examiner takes the position that “(a), (b) and (c) being present in ratios which result in gelling” recited in the instant claims “means simply that the formulation contains the ingredients in ratios such that the formulation “results” (i.e. is ultimately) in a gel. Since the compositions of Guskey contain a gelling agent, any ratio of these ingredients will result in the formulation gelling.” The Examiner further asserts that “so long as the formulation is in the form of a gel, then the ratio of the ingredients resulted in the in gelling. Applicant’s argument would have merit if one were to read “results in” in the limitation as “causes”, which narrower [*sic*] than the broadest reasonable interpretation consistent with the specification”. Paragraph bridging pages 8

and 9 of the instant Office Action.

Applicants respectfully and strongly disagree with the Examiner in this regard as well. In particular, the Examiner appears to be alleging that the instant claims have to interpreted to mean that components (a), (b) and (c) can be present in any ratio, so long as the claimed formulation is a gel. This allegation clearly cannot be reconciled with the language “(a), (b) and (c) being present in ratios which result in gelling” recited in the instant claims. If all that were to matter is that (i) components (a), (b) and (c) are present in the formulation and (ii) the formulation is a gel then “(a), (b) and (c) being present in ratios which result in gelling” should have been replaced by “the formulation being present as a gel” because there would be no reason to mention (a), (b) and (c), let alone the ratios thereof, in the context of gelling. Also, the instant claims already recite that (a), (b) and (c) are present, wherefore there would be no reason to repeat this fact.

Applicants also disagree that the language “in ratios which result” can be ignored and that the ratios of (a), (b) and (c) should be considered to result in (be responsible for) the formation of a gel even if the ratios would not result in gelling but a gel is formed nevertheless due to the use of a separate gelling agent.

It further is pointed out that according to, for example,

<http://www.merriam-webster.com/dictionary/result> the definition of “to result” is:

a : to proceed or arise as a consequence, effect, or conclusion <death *resulted* from the disease>

b : to have an issue or result <the disease *resulted* in death>

Accordingly, contrary to what is alleged by the Examiner, the common meaning of “to result” indeed is that a certain event is caused by (is a consequence of) a certain action, etc.

Clearly, in the present claims “gelling” is linked to the ratios of (a), (b) and (c) by “which result in”, leaving no other reasonable interpretation than that the ratios of (a), (b) and (c) cause gelling, i.e., a gel is formed due to the mere presence of (a), (b) and (c) in suitable ratios, i.e., regardless of whether or not a (another) gelling agent is present.

It is submitted that neither of BHAKOO nor HEI are able to cure the above-noted deficiencies of GUSKEY, and neither has the Examiner made any allegations in this regard.

It further is pointed out again that GUSKEY mentions aluminum or aluminum-zirconium chlorohydrate and mandelic acid as but two examples of the many types of active agents which may be present in the compositions disclosed therein (i.e., antiseptic or antibacterial actives, antifungal agents, hormones, exfoliating agents, topical analgesics, sunscreen actives, antidandruff agents, antioxidants and vitamins, to name but a few) and it is not seen that GUSKEY provides an apparent reason for one of ordinary skill in the art to employ mandelic acid and an antiperspirant active such as aluminum or aluminum-zirconium chlorohydrate in combination.

In addition, mandelic acid is mentioned in GUSKEY as an example of an exfoliating agent whereas aluminum and aluminum-zirconium chlorohydrates are mentioned in GUSKEY as examples of antiperspirant actives which may be present in the compositions taught therein (see col. 5, lines 34-50 and col. 7, lines 40-47 of GUSKEY). It is not seen that one of ordinary skill in the art has an apparent reason to include an antiperspirant active in a composition for exfoliating the skin or to include an exfoliating agent in an antiperspirant.

Applicants note that in this regard the Examiner now relies upon BHAKOO and HEI and alleges that “the skilled artisan would have been motivated to use mandelic acid because Bhakoo et al. teach that malodor is the result of microorganisms that biotransform sweat to produce volatile

odoriferous compounds (paragraph 2) and that generally deodorants work through an antimicrobial ability to decrease the population of microorganisms (paragraph 6). Since Hei et al. teach that mandelic acid possesses antimicrobial properties (column 10, lines 22-63), it would have been obvious to use mandelic acid as a deodorant active agent in combination with an antiperspirant active agent in the composition of Guskey et al.”

In response to these allegations, Applicants note that HEI merely teaches antimicrobial compositions which contain antimicrobially active solvents as set forth in col. 7, lines 1-45 thereof and preferably contain an (optional) additional antimicrobial agent which can be dissolved or dispersed in the antimicrobially-active solvent or in the diluting solvent (col. 10, lines 22-25). Mandelic acid is included in a laundry list of specific compounds and types of compounds of most diverse structures which may be used as additional antimicrobial agent.

Further, according to the paragraph bridging columns 10 and 11 of HEI compositions which contain “such optional additional antimicrobial agents appear to have substantially greater antimicrobial effectiveness than comparison aqueous solutions or dispersions containing the additional antimicrobial agent alone.”

In other words, HEI makes it clear that if used alone, compounds such as, e.g., mandelic acid are not particularly effective as antimicrobial agents, and HEI clearly fails to teach or suggest that mandelic acid by itself would be useful as deodorant.

It further is pointed out that although HEI discloses a large number and variety of potential uses for the antimicrobial compositions disclosed therein (see col. 11, line 58 to col. 13, line 32) the application of these compositions to human skin is not taught or suggested. The closest disclosure in this regard appears to be in col. 12, lines 28-30 of HEI where it is stated that “[t]he antimicrobial

compositions of the invention can be used for treating skin diseases on animals (especially mammals)”.

In this regard, it also must not be forgotten that mandelic acid is mentioned in GUSKEY as an example of an exfoliating agent. Accordingly, even if one were to assume, *arguendo*, that HEI teaches that mandelic acid has deodorizing properties (which HEI fails to do), the fact that mandelic acid also has exfoliating properties would clearly be a disincentive rather than a motivation to employ it in an antiperspirant composition. (Neither has the Examiner provided any evidence which would support an allegation that antiperspirants usually contain exfoliating agents.) This disincentive is not alleviated or “neutralized” by the disclosure of HEI because HEI fails to teach the application of the compositions disclosed therein to human skin (let alone for deodorizing purposes).

Applicants submit that for at least all of the foregoing reasons and the additional reasons set forth in the responses to the previous Office Actions and the Appeal Brief filed March 29, 2010, the rejection of claims 34-57 under 35 U.S.C. § 103(a) over GUSKEY in view of BHAKOO and HEI is unwarranted, wherefore withdrawal thereof is respectfully requested.

Response to Provisional Rejections of Claims

Claims 34-36, 38-45 and 47 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 46-56 and 64 of copending Application No. 10/574,219; claims 34-36 and 38-45 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 46-48, 54-61 and 63 of copending Application No. 10/574,230; and claims 34-36, 38-45 and 47 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as

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allegedly being unpatentable over claims 43, 51-53, 56-59, 64, 75 and 81 of copending Application No. 11/586,585.

Applicants again respectfully request that the above provisional rejections be held in abeyance until the Examiner has indicated allowable subject matter. Applicants will then decide whether the filing of one or more terminal disclaimers is appropriate.

CONCLUSION

In view of the foregoing, it is believed that all of the claims in this application are in condition for allowance (with the possible exception of obviousness-type double patenting issues). If any issues yet remain which can be resolved by a telephone conference, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

Respectfully submitted
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